washwell STRIP

ELISA Strip Washer

User Manual

Version No.:- 03.1

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washwell STRIP, Version – 03.1

1. GENERAL INFORMATION

1.1. Warranty Information:

Each Instrument is completely tested and guaranteed for twelve months from delivery. The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use, and maintenance in compliance with the instructions given in this manual.

ROBONIK will, at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and material damages, caused by improper use or maintenance of the instrument.

Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any travel and man-hour expenses will be charged extra.

1.2. Technical Service:

ROBONIK is always accessible to the customers for any kind of information about installation, use, maintenance, etc. When asking for service, please refer to this manual, and report the data reported on the identification label (Serial No. and Model Name).

Only qualified technicians are entitled to fix the instrument; the user, as described in this manual, should carry out ordinary maintenance.

ROBONIK's technical service or an authorized service center with specialized technicians, with suitable instrumentation and original spare parts are always available for extraordinary maintenance (repair), under an annual maintenance contract or on specific demand.

1.3. Disposal instruction:

In case of removal or disposal of instrument, following instructions need to be followed

- Do not dispose in municipal waste; follow local regulations for instrument disposal.
- Plastic parts, Electronic PCBs and components can be recycled, so return back the instrument to manufacturer.

1.4. Contacts:

Manufacturer:

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MAHAPE, NAVI MUMBAI – 400710
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Tel: +91-22-67829700,
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E-Mail : mail@obelis.net

CE

2. GENERAL SAFETY WARNINGS

2.1. Danger – Warning symbols

The following symbols are used to inform the user of the safety rules.

This symbol indicates generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.

This symbol indicates HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the Supply.

This symbol indicates that the instrument makes use of chemical reagents and other dangerous (Corrosive, irritant, or harmful) CHEMICAL SUBSTANCES, which can cause damage to people or materials. When this label is found, pay attention to the manufacturer's recommendations.

This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use Protective clothes, gloves and glasses.

This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not followed.

This symbol indicates a portion, which is particularly important, and should be studied carefully.

This symbol indicates a Protective Earth or Ground terminal.

General Symbols

Symbol for "Manufacturer"

Symbol for " IN VITRO DIAGNOSTIC MEDICAL DEVICE"

Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

2.2. Use of the instrument:

- The instrument should be used for the designed purposes only and under specified conditions by qualified personnel, following proper procedures and safety rules provided in this manual.

- **THIS MANUAL CONTAINS INSTRUCTIONS FOR OPERATION BY QUALIFIED PERSONNEL ONLY.**

- A qualified user has to make sure that environmental condition is suitable, the installation correct, the use and maintenance is proper, according to the general safety rules as well as to the particular precautions described in the manual (However the user is not entitled to repair the instrument).

- A qualified technician only, is entitled to maintain and fix the instrument, according to the instructions given in this manual, using the original spare parts only.

- The room temperature and humidity should be maintained as specified in the manual.

- The instrument has to be used as described in this manual. If it is not use the protection provided by the instrument may be impaired.

- **Alterations to the instrument by unauthorized personnel are strictly prohibited. The user is liable & solely responsible for any improper modification to the instrument, and for the consequences derived as a result.**

- Should the instrument need extraordinary maintenance, please contact Robonik service or an authorized service center. Specialized technicians equipped to repair the instrument using original spare parts will carry out the maintenance.

- This IVD equipment complies with the emission and immunity requirements as per IEC61326 series.

- **Warning :** This equipment has been designed and tested to CISPER11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."

- An advisory that the electromagnetic environment should be evaluated prior to operation of the device.

- **Warning :** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded international RF sources), as these may interfere with the proper operation.

3. INTRODUCTION

3.1. Description:

Washwell STRIP is an automatic ELISA strip washer with optional built-in Incubator & programmable timer. Its unique co-axial probe allows user to wash single well or a strip with user defined number of wash cycles, soak time, wash volume etc.

It is designed to be used to wash single or multiple wells by automated procedure, Hence eliminating errors in assays rising due to cumbersome manual wash method. It is intended for in vitro diagnostic use.

3.2. Special Features:

- Built-in stabilizer.
- Ability to wash single well / Multiple wells.
- Waste bottle with acoustic signal for bottle full indication.
- Ability to wash U, V and Flat bottom wells.
- Overflow protection through continuous aspiration.
- Cross wash facility.
- Auto detection of bottom of well and collision prevention.
- Optional built-in Incubator 37^0C (Factory set) with programmable timer.

3.3. Specifications:

Device	High quality stainless steel co-axial probe.
Dispensing Method **Volume**	Specially designed Peristaltic pump 25 to 400 µl
Aspirating Method **Residual Volume**	Continuous through diaphragm pump < 3 µl
Waste Bottle	One (Capacity 1 liter) with audible alarm
Wash Bottle	One (Capacity 1 liter)
Rinse Bottle	One (Capacity 1 liter)
Memory	35 Open Channels
Display	Single line backlit LCD, 16 characters
Number of Wash cycle	1 to 99
Soak Time	1 to 999 sec.
Liquid contact materials	Silicon, Stainless Steel, Derline
Washing Method	Well Wash / Short Wash Strip Wash / Long Wash Cross Wash Rinsing Priming
Incubator (Optional)	For One ELISA Plate, 37^0C
Weight	4 Kg.
Size (cms)	32 x 35 x 11.5 (l x b x h)

4. PACKING, TRANSPORT AND STORAGE

4.1. Packing:

Packaging of the instrument is needed whenever to be transported or shipped by courier or other means.

To pack the instrument please follow the instructions as below described:

- Decontaminate the instrument as explained on chapter 11 of this manual.
- Put the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of safety clearance certificate (copy of Safety clearance certificate is attached at the end of this manual).
- Mark the package with address, instrument identification and warning labels.

4.2. Instrument transportation:

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.3. Storage of the instrument:

Before storing the instrument for a long period, please pack it carefully as described above and store indoors.

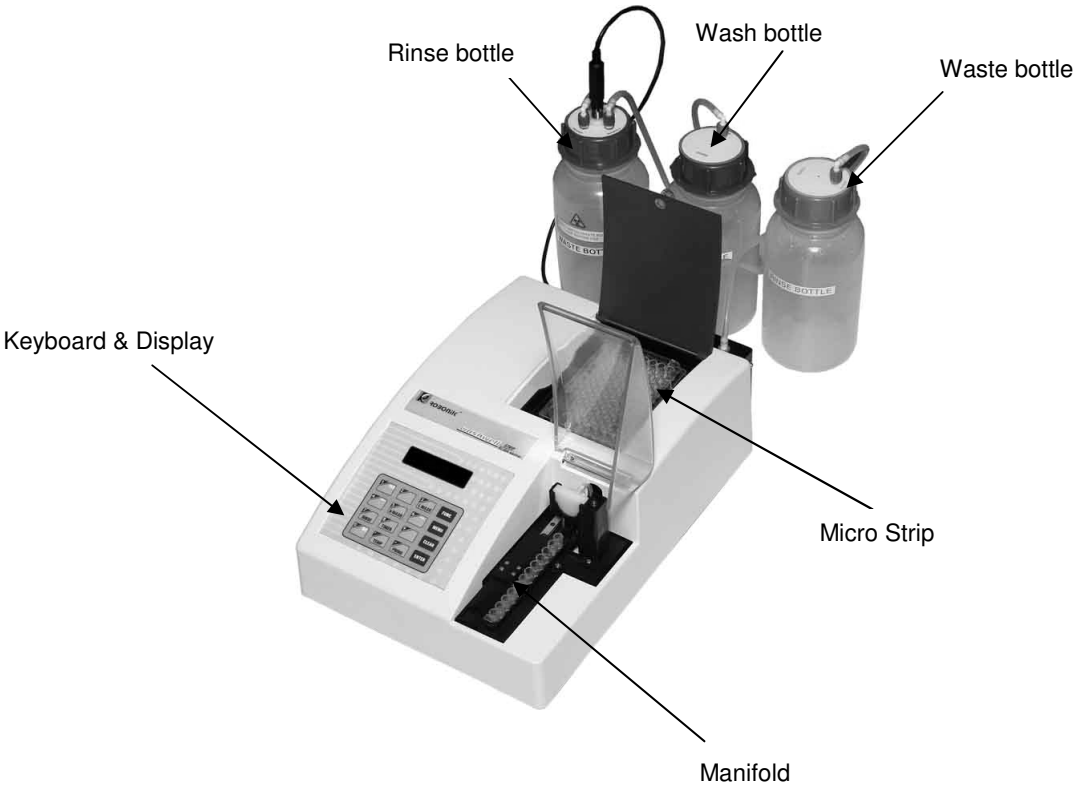
5. INSTRUMENT DESCRIPTION

Components of different views of the instrument in picture below:

5.1. Perspective View:

Front view

- Display,
- Alphanumerical key-pad
- Wash Bottle
- Waste Bottle
- Rinse Bottle



5.2. Rear Panel View:

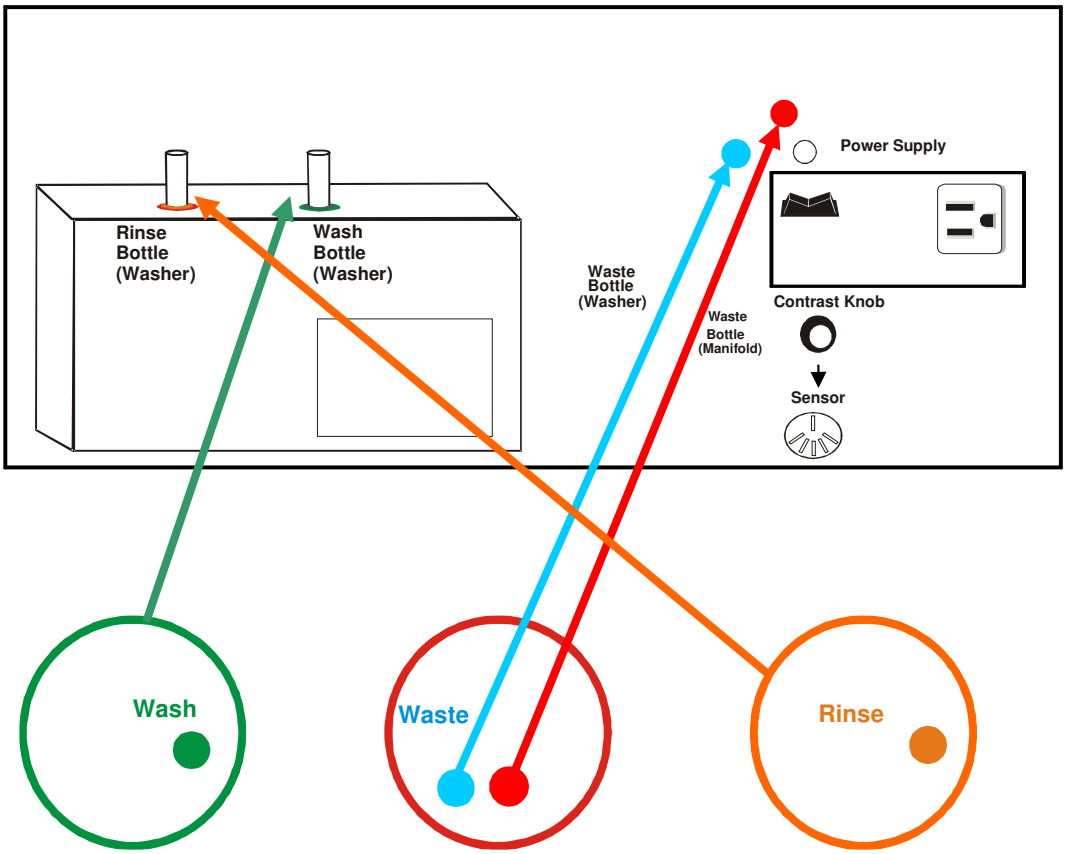
(Please refer diagram of point No. 5.3)

- Ensure that the main power switch is in **OFF** position before connecting.
- Plug the instrument to the **A C** mains. Confirm proper grounding for trouble free operation.

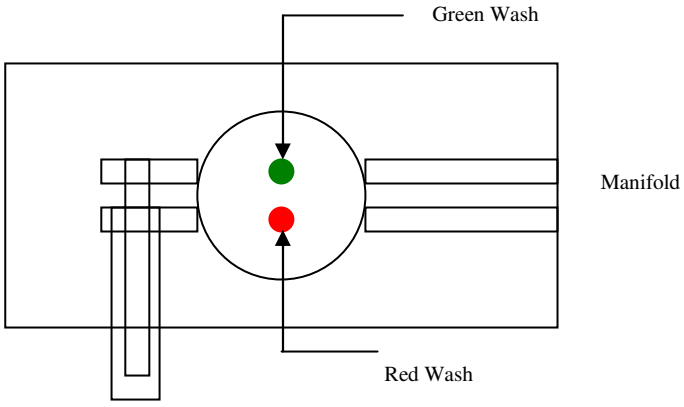
The washwell STRIP is provided with an inbuilt voltage stabilizer to take care of voltage fluctuations.

5.3. Tubing Diagram:

REAR PANEL TUBING CONNECTIONS

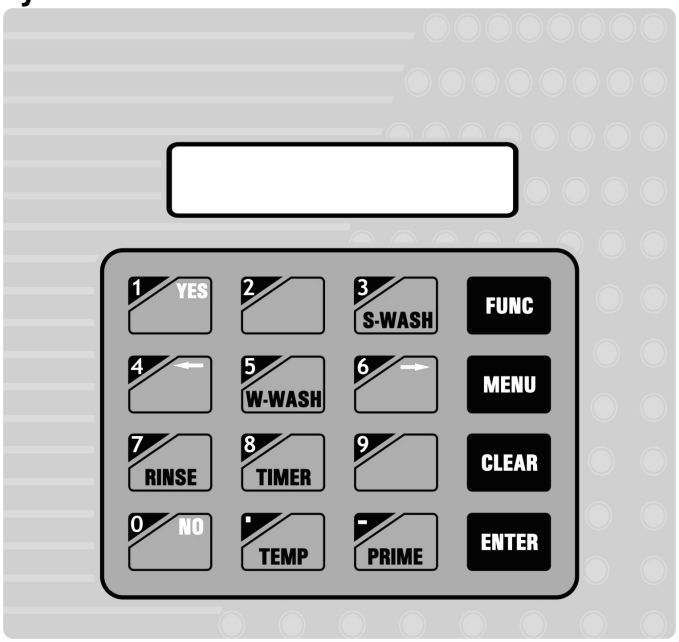


MANIFOLD TUBING CONNECTIONS



Note : Load Elisa Strip carefully in the slot provided for correct washing

5.4. Keyboard:

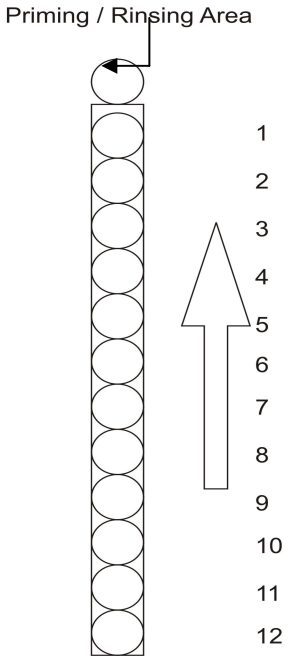


5.5. Priming Area:

Carriage Strip has a built-in priming area.
Priming is essential immediately after starting the instrument, and before shutting down the instrument. It helps smooth flow of buffer and prevents crystallization.

5.6. Micro-Strip Carriage:

Movement of Strip is precisely controlled by stepper motor and timing belt to position the Strip exactly below the manifold for washing
(Ref Fig a)



5.7. Priming and Rinsing Area:

Carriage Strip has built-in priming and rinsing area, priming and rinsing is essential immediately after starting the instrument, and before shutting down the instrument. It helps smooth flow of buffer solution and prevents crystallization. (Ref Fig a)

5.8. Manifold:

Instrument has a specially designed 1-way manifold.

The manifold has a provision to clean the liquid path conveniently hence avoiding common clogging problem because of crystallization, etc.

Manifold is moved vertically up and down by well-controlled stepper motor for proper placement. Manifold needles are laboratory grade steel smooth ends to prevent scratching of the well bottom.

6. INSTALLATION AND START-UP INSTRUCTIONS

While installing and setting up the instrument, the safety warnings and general precautions described in section 8 must be observed.

6.1. Placing the instrument:

- The instrument has to be placed on a level bench
- A min. distance of 1m should be maintained from the rear panel to avoid damage to power cord and instrument
- Room temperature has to be between 18ºC and 35ºC with a relative humidity below 85%.
- Protect it from direct sunshine.

6.2. Power supply:

Once the instrument has been placed, plug it into a power source by the locally available approved plug-in cable. Power cord should be CE, CSA and UL marked.

Voltage -115 - 230 Volts ± 10%, 50- 60 Hz

6.3. Protective Grounding:

Warning: Please make sure that electrical power source is properly grounded.

6.4. Start up Instructions

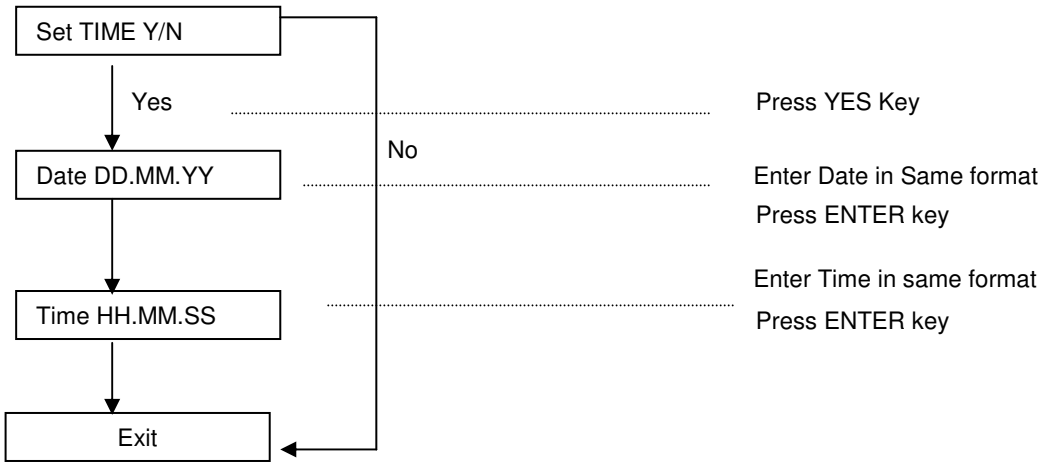
Instrument Starting Procedure

1. Switch on the instrument. The instrument will display WASH WELL.
2. The instrument carries out a Power on Self Test to check all the internal parameters.
3. It displays **ROBONIK** and the time indicating that initialization is complete.
4. If the date and time are not correctly displayed, switch off the instrument and switch it on once again.

The instrument is now ready for use.

6.5. Setting date and time:

Setting of date and time can be done with the help of FUNC key



6.6. Waste Bottle connections:

Please refer point No. 5.3, Tubing Diagram.

7. PRECAUTIONS

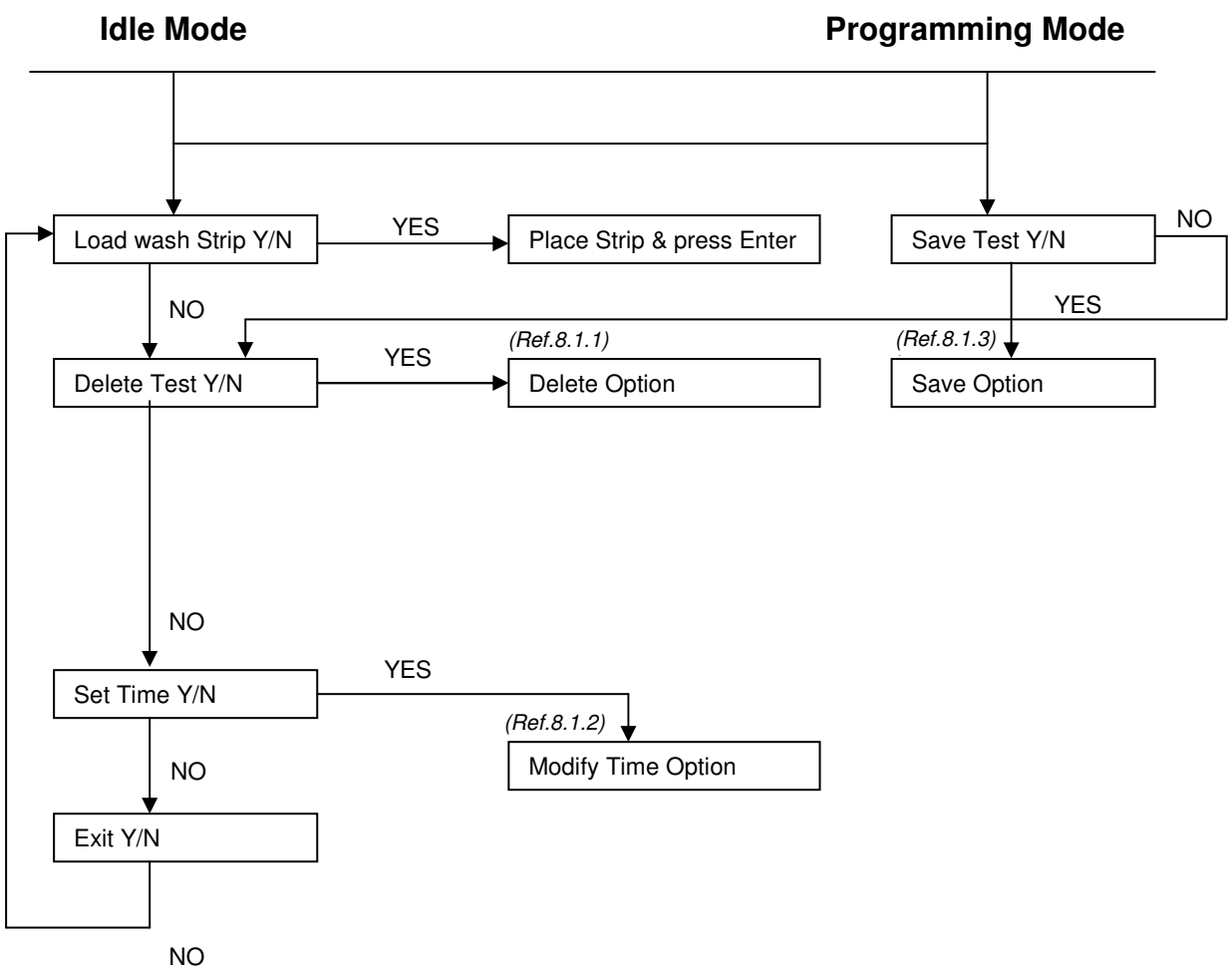
- Always check for proper grounding, during installation. Never operate the instrument with ground wire removed.
- Do not attempt to open the instrument and make repair without proper technical training. Do not allow unauthorized persons to operate or repair the instrument.

  Place the ELISA Strip carefully on the tray
- Ensure that the main power switch is in OFF position before connecting.
- Prime the manifold before and after use.
- Always Prime immediately after switching ON the instrument.
- Always rinse before switching OFF.
- Keep wash, waste and rinse bottles clean.
- Disconnect the tubing before opening wash, waste and rinse bottle caps.

8. GENERAL KEY OPERATIONS

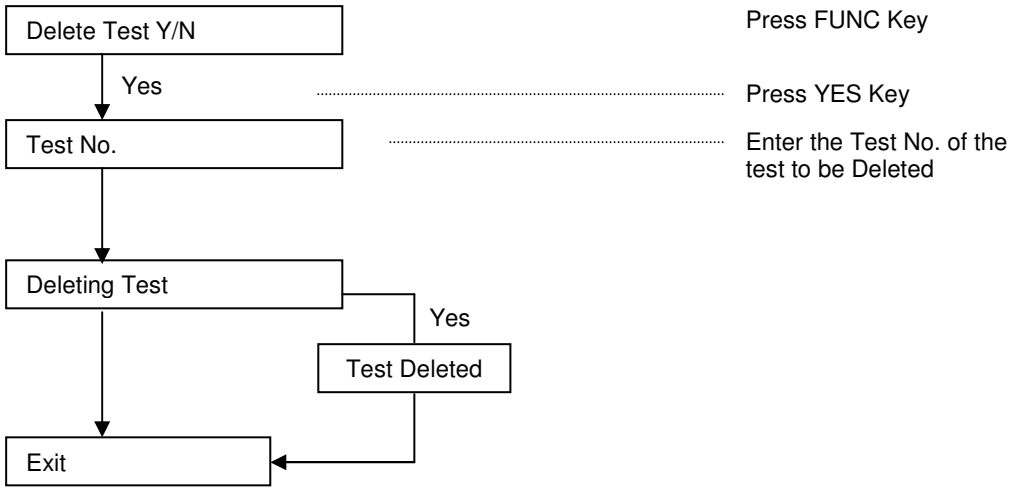
Check whether all the tubing is properly connected. Switch on the instrument.

8.1. FUNC KEY FUNC



8.1.1 Deleting test

Display **How to operate**



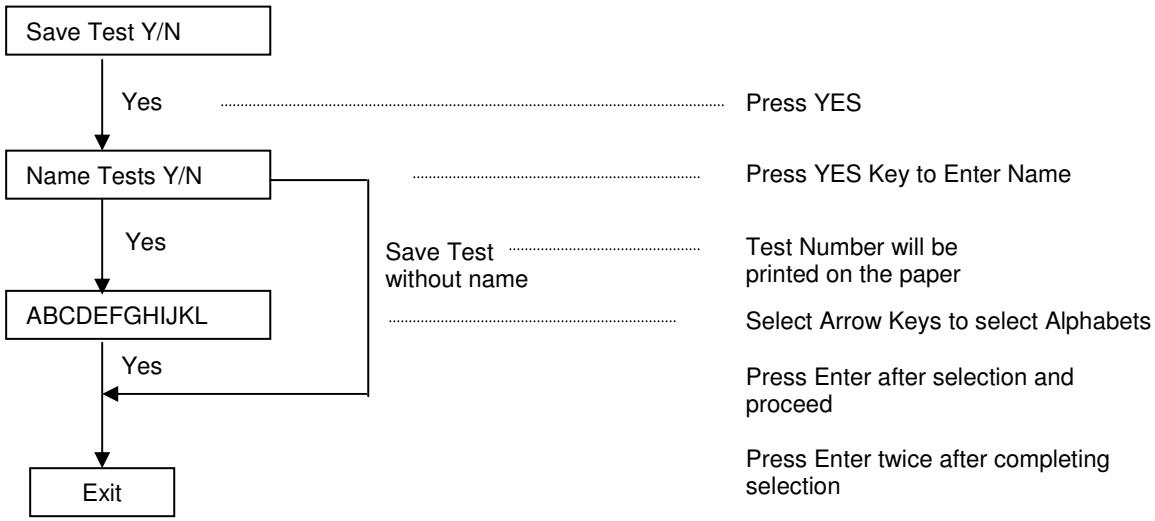
8.1.2. Setting Date and Time

(Refer point No. 6.5)

8.1.3. Storing the Test:

To save the programmed test under any programming Mode

Display **How to operate**



8.2. MENU KEY:

This key is used to recall the test number to be performed.

8.2.1. Recalling the saved test:

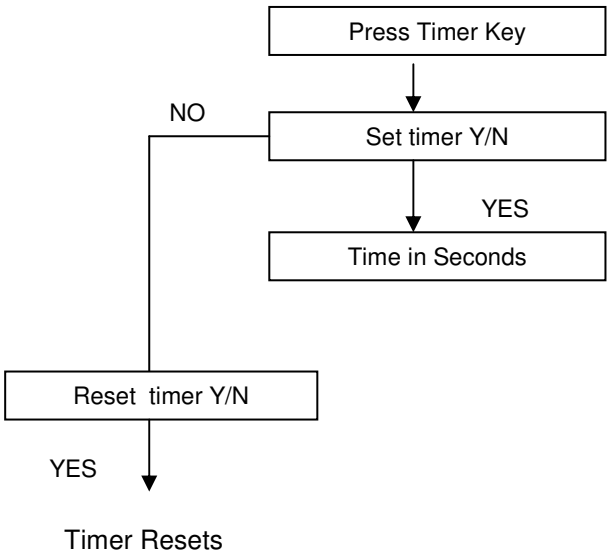
8.3. PRIME KEY:

Pressing the 'Prime key', Peristaltic pump#1 operates continuously for few seconds. Wash buffer from wash bottle primes the tubing and manifold needles.

8.4. RINSE KEY:

Pressing Rinse key peristaltic pump 2 operates continuously for few seconds. Distilled water from rinse bottle, rinses the tubing and manifold needles.

8.5. TIMER KEY:



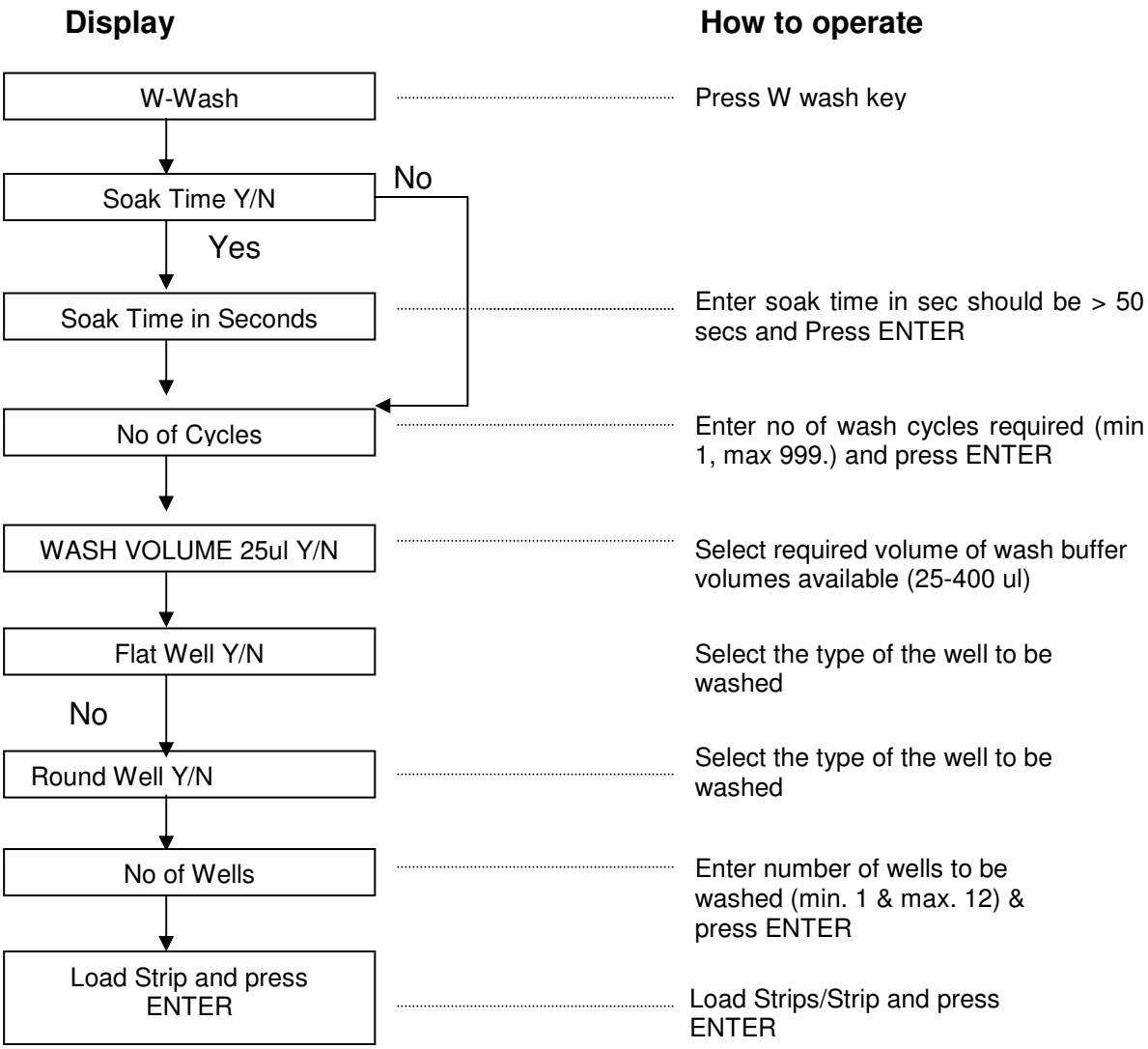
9. PROGRAMMING

9.1. Strip Wash:

Display	How to operate
S-Wash	Press S wash key
Soak Time in Seconds	Enter soak time in sec should be >50 secs and Press ENTER
No of Cycles	Enter no of wash cycles required (min 1, max 999.) and press ENTER
WASH VOLUME 25 ul Y/N	Select required volume of wash buffer volumes available (25-400 ul)
Flat Well Y/N	Select the type of the well to be washed
No	
Round Well Y/N	Select the type of the well to be washed
No of Wells	Enter number of Wells to be washed (min. 1 max. 12) & press ENTER
Load Strip and press ENTER	Load Strips/Strip and press ENTER

Instrument aspirates the waste solution from the well. Dispenses the programmed volume in to the micro-strip well. Aspiration is continuously kept 'on' to prevent the over flow. After completing dispensing cycle, depending on soak time it starts aspirating the solution. After this the instrument transports the micro-Strip back to home position.

9.2. Well Wash:


Display
How to operate
W-Wash
Press W wash key
Soak Time Y/N
No
Yes
Soak Time in Seconds
Enter soak time in sec should be > 50 secs and Press ENTER
No of Cycles
Enter no of wash cycles required (min 1, max 999.) and press ENTER
WASH VOLUME 25ul Y/N
Select required volume of wash buffer volumes available (25-400 ul)
Flat Well Y/N
Select the type of the well to be washed
No
Round Well Y/N
Select the type of the well to be washed
No of Wells
Enter number of wells to be washed (min. 1 & max. 12) & press ENTER
Load Strip and press ENTER
Load Strips/Strip and press ENTER

Instrument aspirates the waste solution from the well. Dispenses the programmed volume in to the micro-strip well. Aspiration is continuously kept on to prevent the over flow. After completing dispensing cycle, depending on soak time it starts aspirating the solution. After this the instrument transports the micro-Strip back to home position.

9.3. Incubation:

WASH WELL consists of a One Plate incubator which can be programmed individually. After the set time elapses, the instrument gives an audible alarm as well as notification on display indicating the elapse of time. Both the timers can be programmed separately.

Incubator is activated when the instrument is in power on condition. It takes 10-15 minutes to attain 37º C Temperature (This temperature is factory set).

Procedure to program incubator time is as follows:

(Please refer point No. 8.5)

9.4. Priming:

(Please refer point No. 8.3)

9.5. Rinsing:

(Please refer point No. 8.4)

10. TROUBLESHOOTING

PROBLEM	SOLUTION
The Manifold does not dispense	• Clean the path of the steel tubes using needle cleaner provided. • Check Wash bottle tubing connections. • Check valve direction.
The Manifold does not aspirate	• Clean the path of the steel tubes using needle cleaner provided. • Check the Waste bottle cap and tighten them properly. • Check waste bottle tubing connections.
The Instrument beeps continuously	• Check the Sensor cable connection. • Check whether waste bottle is full. • Check the waste bottle cap and clean the cap.
Movement Jam	Reset the instrument by pressing the CLEAR key twice or Switch OFF and Switch ON the instrument. Insert the Strip properly and return.
Memory Full	If Number of saved tests exceeds 35 tests then delete the unwanted test and save the test.

11. DECONTAMINATION

Check whether all the tubing is properly connected. Switch on the instrument.

11.1. Decontamination procedure:

If the instrument is to be shipped after being exposed to potentially hazardous material, it should be decontaminated. The following procedure outlines the method to decontaminate the instrument before packaging and shipment.

11.2. Purpose of Decontamination:

Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

11.3. General Considerations:

- Any laboratory instrument that has been used for clinical analysis is considered a bio-hazard and should be decontaminated prior to handling. Intact skin is generally considered an effective barrier against infectious organisms; however, small abrasions and cuts may not be always visible. Prophylactic gloves must be worn when handling instruments that have not been decontaminated. Gloved hands should be considered contaminated and must be kept away from eyes mouth and nose at all times.

- Mucous membranes are considered as the prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.

- Eating and/or drinking while decontaminating instruments is not advisable.

11.4. Decontamination procedure:

- A solution of 0.5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.

- Wipe down the carrier and all exposed surfaces of the unit with the bleach solution. Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.

- Reassemble the unit and discard the used gloves and towels.

12. SAFETY CLEARANCE CERTIFICATE:

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your co-operation.

Customer _____ Contact _____

Address _____ Position _____

_____ Dept _____

_____ Tel: _____

Country _____ Fax: _____

Post Code _____

Model No. _____ Serial No. _____

Accessories Returned _____

_____

_____

Date of Purchase (if known) _____

Complaint _____

_____

_____

Has the equipment been exposed to any of the following: (*delete as applicable)

a) Blood, body fluids, pathological specimens *YES/NO
If YES, please specify _____

_____

b) Other Biohazard *YES/NO
if YES, Please specify _____